HOUSE BILL No. 1278

DIGEST OF INTRODUCED BILL

Citations Affected: IC 25; IC 35-48-7.

Synopsis: INSPECT program. Requires a dentist, physician, advanced practice nurse, physician assistant, and podiatrist to check the INSPECT program before prescribing or issuing a refill for a Schedule II controlled substance or a Schedule III controlled substance except in certain circumstances. Requires a pharmacist who is aware of certain circumstances to check the INSPECT program before dispensing a Schedule II controlled substance or a Schedule III controlled substance. Allows a county coroner conducting a medical investigation of the cause of death to access the INSPECT program. Makes certain changes to the immunity granted to practitioners who use the INSPECT program. (Current law extends immunity to both practitioners who use and do not use the INSPECT program.) Requires boards that regulate health care providers that prescribe or dispense prescription drugs to establish prescribing norms and dispensing guidelines that, if violated, justify the unsolicited dissemination of exception reports. Provides that the exception reports may only be forwarded for an investigation by a law enforcement agency or the attorney general. Makes a technical correction.

Effective: July 1, 2016; March 1, 2017; July 1, 2017.

Davisson

January 12, 2016, read first time and referred to Committee on Public Health.

Introduced

Second Regular Session of the 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

HOUSE BILL No. 1278

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 25-14-1-1.5, AS AMENDED BY P.L.103-2011, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 1.5. The following definitions apply throughout this article:

(1) "Agency" refers to the Indiana professional licensing agency established by IC 25-1-5-3.

(2) "Board" refers to the state board of dentistry established under this chapter.

(3) "Deep sedation" means a drug induced depression of consciousness during which cardiovascular function is usually maintained and the individual may:

(A) not be easily aroused;

(B) be able to respond purposefully following repeated or painful stimulation;

(C) have an impaired ability to independently maintain ventilatory function;

(D) require assistance in maintaining a patent airway; and

(E) have inadequate spontaneous ventilation.

(4) "Dental assistant" means a qualified dental staff member, other than a licensed dental hygienist, who assists a licensed dentist with patient care while working under the dentist's direct supervision.

(5) "Direct supervision" means that a licensed dentist is physically present in the facility when patient care is provided by the dental assistant.

(6) "Enteral route of administration" means a technique of administering an agent so that it is absorbed through the gastrointestinal tract or oral mucosa.

(7) "General anesthesia" means a drug induced loss of consciousness during which cardiovascular function may be impaired and the individual:

(A) is not arousable, even by painful stimulation;

(B) often has an impaired ability to independently maintain ventiliatory function;

(C) often requires assistance in maintaining a patent airway; and

(D) may require positive pressure ventilation because of depressed spontaneous ventilation or drug induced depression of neuromuscular function.

(8) "INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.

~~(8)~~ **(9)** "Moderate sedation" means a drug induced depression of consciousness during which cardiovascular function is usually maintained and the individual:

(A) responds purposefully to verbal commands, either alone or with light tactile stimulation;

(B) does not require intervention to maintain a patent airway; and

(C) has adequate spontaneous ventilation.

~~(9)~~ **(10)** "Parenteral route of administration" means a technique of administering an agent by intravenous or intramuscular injection so that it bypasses the gastrointestinal tract.

SECTION 2. IC 25-14-1-23.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 23.5. (a) In addition to the rules adopted under IC 25-22.5-13-3, before initially prescribing a Schedule II controlled substance or a Schedule III controlled substance to a patient, a dentist shall:**

(1) check the INSPECT program for the available data on the patient for the twelve (12) month period immediately preceding the patient encounter; and

(2) appropriately use the INSPECT program data in the evaluation and treatment of a patient.

(b) If a patient's course of treatment with a Schedule II controlled substance or a Schedule III controlled substance prescribed by the dentist extends beyond three (3) months, a dentist shall:

(1) check the INSPECT program not less than every four (4) months for the available data on the patient for the preceding twelve (12) month period; and

(2) review the available INSPECT program data before issuing any new prescription or refills for the patient for a Schedule II controlled substance or a Schedule III controlled substance.

(c) If the INSPECT program data is not immediately available when the dentist is conducting a check under subsection (a) or (b), the dentist shall use the dentist's professional judgment in determining whether it is appropriate and in the patient's best interest to prescribe a Schedule II controlled substance or a Schedule III controlled substance before receiving and reviewing the INSPECT program data.

(d) The requirements under subsections (a) and (b) do not apply in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

SECTION 3. IC 25-22.5-1-1.1, AS AMENDED BY P.L.158-2013, SECTION 283, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2017]: Sec. 1.1. As used in this article:

(a) "Practice of medicine or osteopathic medicine" means any one (1) or a combination of the following:

(1) Holding oneself out to the public as being engaged in:

(A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, pain, or other condition of human beings;

(B) the suggestion, recommendation, or prescription or administration of any form of treatment, without limitation;

(C) the performing of any kind of surgical operation upon a human being, including tattooing (except for providing a tattoo as defined in IC 35-45-21-4(a)), in which human tissue is cut, burned, or vaporized by the use of any mechanical means, laser, or ionizing radiation, or the penetration of the skin or body orifice by any means, for the intended palliation, relief, or cure; or

(D) the prevention of any physical, mental, or functional ailment or defect of any person.

(2) The maintenance of an office or a place of business for the reception, examination, or treatment of persons suffering from disease, ailment, defect, injury, infirmity, deformity, pain, or other conditions of body or mind.

(3) Attaching the designation "doctor of medicine", "M.D.", "doctor of osteopathy", "D.O.", "osteopathic medical physician", "physician", "surgeon", or "physician and surgeon", either alone or in connection with other words, or any other words or abbreviations to a name, indicating or inducing others to believe that the person is engaged in the practice of medicine or osteopathic medicine (as defined in this section).

(4) Providing diagnostic or treatment services to a person in Indiana when the diagnostic or treatment services:

(A) are transmitted through electronic communications; and

(B) are on a regular, routine, and nonepisodic basis or under an oral or written agreement to regularly provide medical services.

In addition to the exceptions described in section 2 of this chapter, a nonresident physician who is located outside Indiana does not practice medicine or osteopathy in Indiana by providing a second opinion to a licensee or diagnostic or treatment services to a patient in Indiana following medical care originally provided to the patient while outside Indiana.

(b) "Board" refers to the medical licensing board of Indiana.

(c) "Diagnose or diagnosis" means to examine a patient, parts of a patient's body, substances taken or removed from a patient's body, or materials produced by a patient's body to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is a physician and is so examining a patient. It is not necessary that the examination be made in the presence of the patient; it may be made on information supplied either

directly or indirectly by the patient.

(d) "Drug or medicine" means any medicine, compound, or chemical or biological preparation intended for internal or external use of humans, and all substances intended to be used for the diagnosis, cure, mitigation, or prevention of diseases or abnormalities of humans, which are recognized in the latest editions published of the United States Pharmacopoeia or National Formulary, or otherwise established as a drug or medicine.

(e) "Licensee" means any individual holding a valid unlimited license issued by the board under this article.

(f) "Prescribe or prescription" means to direct, order, or designate the use of or manner of using a drug, medicine, or treatment, by spoken or written words or other means.

(g) "Physician" means any person who holds the degree of doctor of medicine or doctor of osteopathy or its equivalent and who holds a valid unlimited license to practice medicine or osteopathic medicine in Indiana.

(h) "Medical school" means a nationally accredited college of medicine or of osteopathic medicine approved by the board.

(i) "Physician assistant" means an individual who:

(1) is supervised by a physician;

(2) graduated from an approved physician assistant program described in IC 25-27.5-2-2;

(3) passed the examination administered by the National Commission on Certification of Physician Assistants (NCCPA) and maintains certification; and

(4) has been licensed by the physician assistant committee under IC 25-27.5.

(j) "Agency" refers to the Indiana professional licensing agency under IC 25-1-5.

(k) "INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.

SECTION 4. IC 25-22.5-13-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 7. (a) In addition to the rules adopted under section 3 of this chapter, before initially prescribing a Schedule II controlled substance or a Schedule III controlled substance to a patient, a physician shall:**

(1) check the INSPECT program for the available data on the patient for the twelve (12) month period immediately preceding the patient encounter; and

(2) appropriately use the INSPECT program data in the evaluation and treatment of a patient.

(b) If a patient's course of treatment with a Schedule II controlled substance or a Schedule III controlled substance prescribed by the physician extends beyond three (3) months, a physician shall:

(1) check the INSPECT program not less than every four (4) months for the available data on the patient for the preceding twelve (12) month period; and

(2) review the available INSPECT program data before issuing any new prescription or refills for the patient for a Schedule II controlled substance or a Schedule III controlled substance.

(c) If the INSPECT program data is not immediately available when the physician is conducting a check under subsection (a) or (b), the physician shall use the physician's professional judgment in determining whether it is appropriate and in the patient's best interest to prescribe a Schedule II controlled substance or a Schedule III controlled substance before receiving and reviewing the INSPECT program data.

(d) The requirements under subsections (a) and (b) do not apply in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

(e) If a physician obtains or receives specific information that a patient is not taking a controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the physician may obtain and review a report from the INSPECT program and appropriately use the information in the evaluation and treatment of the patient.

(f) A physician shall document that the physician checked the INSPECT program, as required by this section. A physician may include a report from the INSPECT program in a patient's medical file. Any disclosure or release of a patient's medical file must be in compliance with IC 35-48-7-11.1.

SECTION 5. IC 25-23-1-1.5 IS ADDED TO THE INDIANA CODE

AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 1.5. As used in this chapter, "INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.**

SECTION 6. IC 25-23-1-19.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 19.9. (a) This section does not apply to certified registered nurse anesthetists.**

(b) In addition to the rules adopted under IC 25-22.5-13-3, before initially prescribing a Schedule II controlled substance or a Schedule III controlled substance to a patient, an advanced practice nurse shall:

(1) check the INSPECT program for the available data on the patient for the twelve (12) month period immediately preceding the patient encounter; and

(2) appropriately use the INSPECT program data in the evaluation and treatment of a patient.

(c) If a patient's course of treatment with a Schedule II controlled substance or a Schedule III controlled substance prescribed by the advanced practice nurse extends beyond three (3) months, an advanced practice nurse shall:

(1) check the INSPECT program not less than every four (4) months for the available data on the patient for the preceding twelve (12) month period; and

(2) review the available INSPECT program data before issuing any new prescription or refills for the patient for a Schedule II controlled substance or a Schedule III controlled substance.

(d) If the INSPECT program data is not immediately available when the advanced practice nurse is conducting a check under subsection (b) or (c), the advanced practice nurse shall use the advanced practice nurse's professional judgment in determining whether it is appropriate and in the patient's best interest to prescribe a Schedule II controlled substance or a Schedule III controlled substance before receiving and reviewing the INSPECT program data.

(e) The requirements under subsections (b) and (c) do not apply in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

SECTION 7. IC 25-26-13-2, AS AMENDED BY P.L.89-2015, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 2. As used in this chapter:

"Administering" means the direct application of a drug to the body of a person by injection, inhalation, ingestion, or any other means.

"Board" means the Indiana board of pharmacy.

"Controlled drugs" are those drugs on schedules I through V of the federal Controlled Substances Act or on schedules I through V of IC 35-48-2.

"Counseling" means effective communication between a pharmacist and a patient concerning the contents, drug to drug interactions, route, dosage, form, directions for use, precautions, and effective use of a drug or device to improve the therapeutic outcome of the patient through the effective use of the drug or device.

"Dispensing" means issuing one (1) or more doses of a drug in a suitable container with appropriate labeling for subsequent administration to or use by a patient.

"Drug" means:

(1) articles or substances recognized in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them;

(2) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(3) articles other than food intended to affect the structure or any function of the body of man or animals; or

(4) articles intended for use as a component of any article specified in subdivisions (1) through (3) and devices.

"Drug order" means a written order in a hospital or other health care institution for an ultimate user for any drug or device, issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution. The order shall contain the name and bed number of the patient; the name and strength or size of the drug or device; unless specified by individual institution policy or guideline, the amount to be dispensed either in quantity or days; adequate directions for the proper use of the drug or

device when it is administered to the patient; and the name of the prescriber.

"Drug regimen review" means the retrospective, concurrent, and prospective review by a pharmacist of a patient's drug related history that includes the following areas:

(1) Evaluation of prescriptions or drug orders and patient records for drug allergies, rational therapy contradictions, appropriate dose and route of administration, appropriate directions for use, or duplicative therapies.

(2) Evaluation of prescriptions or drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions.

(3) Evaluation of prescriptions or drug orders and patient records for adverse drug reactions.

(4) Evaluation of prescriptions or drug orders and patient records for proper utilization and optimal therapeutic outcomes.

"Drug utilization review" means a program designed to measure and assess on a retrospective and prospective basis the proper use of drugs.

"Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component part or accessory, which is:

(1) recognized in the official United States Pharmacopoeia, official National Formulary, or any supplement to them;

(2) intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(3) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

"Electronic data intermediary" means an entity that provides the infrastructure that connects a computer system or another electronic device used by a prescribing practitioner with a computer system or another electronic device used by a pharmacy to facilitate the secure transmission of:

(1) an electronic prescription order;

(2) a refill authorization request;

(3) a communication; and

(4) other patient care information;

between a practitioner and a pharmacy.

"Electronic signature" means an electronic sound, symbol, or process:

(1) attached to or logically associated with a record; and

(2) executed or adopted by a person;

with the intent to sign the record.

"Electronically transmitted" or "electronic transmission" means the transmission of a prescription in electronic form. The term does not include the transmission of a prescription by facsimile.

"INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.

"Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

"Legend drug" has the meaning set forth in IC 16-18-2-199.

"License" and "permit" are interchangeable and mean a written certificate from the Indiana board of pharmacy for the practice of pharmacy or the operation of a pharmacy.

"Medication therapy management" means a distinct service or group of services that optimize therapeutic outcomes for individuals that are independent of, but may occur in conjunction with, the provision of a medication or medical device. The term includes the following services:

(1) Performing or obtaining assessments of an individual's health status.

(2) Formulating a medication treatment plan.

(3) Selecting, initiating, modifying, or administering medication therapy.

(4) Monitoring and evaluating an individual's response to therapy, including safety and effectiveness.

(5) Performing a comprehensive medication review to identify, resolve, and prevent medication related problems, including adverse drug events.

(6) Documenting the care delivered and communicating essential information to the patient's other health care providers.

(7) Providing education and training designed to enhance patient understanding and appropriate use of the individual's medications.

(8) Providing information and support services and resources designed to enhance patient adherence with the individual's therapeutic regimens, including medication synchronization.

(9) Coordinating and integrating medication therapy management services within the broader health care services being provided to

an individual.

(10) Providing other patient care services allowable by law.

"Nonprescription drug" means a drug that may be sold without a prescription and that is labeled for use by a patient in accordance with state and federal laws.

"Person" means any individual, partnership, copartnership, firm, company, corporation, association, joint stock company, trust, estate, or municipality, or a legal representative or agent, unless this chapter expressly provides otherwise.

"Practitioner" has the meaning set forth in IC 16-42-19-5.

"Pharmacist" means a person licensed under this chapter.

"Pharmacist intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"Pharmacy" means any facility, department, or other place where prescriptions are filled or compounded and are sold, dispensed, offered, or displayed for sale and which has as its principal purpose the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public, without placing any other activity on a more important level than the practice of pharmacy.

"The practice of pharmacy" or "the practice of the profession of pharmacy" means a patient oriented health care profession in which pharmacists interact with and counsel patients and with other health care professionals concerning drugs and devices used to enhance patients' wellness, prevent illness, and optimize the outcome of a drug or device, by accepting responsibility for performing or supervising a pharmacist intern or an unlicensed person under section 18.5 of this chapter to do the following acts, services, and operations:

(1) The offering of or performing of those acts, service operations, or transactions incidental to the interpretation, evaluation, and implementation of prescriptions or drug orders.

(2) The compounding, labeling, administering, dispensing, or

selling of drugs and devices, including radioactive substances, whether dispensed under a practitioner's prescription or drug order or sold or given directly to the ultimate consumer.

(3) The proper and safe storage and distribution of drugs and devices.

(4) The maintenance of proper records of the receipt, storage, sale, and dispensing of drugs and devices.

(5) Counseling, advising, and educating patients, patients' caregivers, and health care providers and professionals, as necessary, as to the contents, therapeutic values, uses, significant problems, risks, and appropriate manner of use of drugs and devices.

(6) Assessing, recording, and reporting events related to the use of drugs or devices.

(7) Provision of the professional acts, professional decisions, and professional services necessary to maintain all areas of a patient's pharmacy related care as specifically authorized to a pharmacist under this article.

(8) Provision of medication therapy management.

"Prescription" means a written order or an order transmitted by other means of communication from a practitioner to or for an ultimate user for any drug or device containing:

(1) the name and address of the patient;

(2) the date of issue;

(3) the name and strength or size (if applicable) of the drug or device;

(4) the amount to be dispensed (unless indicated by directions and duration of therapy);

(5) adequate directions for the proper use of the drug or device by the patient;

(6) the name of the practitioner; and

(7) if the prescription:

(A) is in written form, the signature of the practitioner; or

(B) is in electronic form, the electronic signature of the practitioner.

"Qualifying pharmacist" means the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operations of the pharmacy under the permit.

"Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records, or other written indicia, documents, or objects which are used in any way in connection with the purchase, sale, or

handling of any drug or device.

"Sale" means every sale and includes:

(1) manufacturing, processing, transporting, handling, packaging, or any other production, preparation, or repackaging;

(2) exposure, offer, or any other proffer;

(3) holding, storing, or any other possession;

(4) dispensing, giving, delivering, or any other supplying; and

(5) applying, administering, or any other using.

SECTION 8. IC 25-26-13-34 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 34. (a) Before dispensing a Schedule II controlled substance or a Schedule III controlled substance to a patient, a pharmacist shall check the INSPECT program if the pharmacist becomes aware that the patient is currently:**

(1) receiving a Schedule II controlled substance or a Schedule III controlled substance from multiple prescribers;

(2) abusing or misusing a Schedule II controlled substance or a Schedule III controlled substance through overuse, early refills, or appearing overly sedated or intoxicated upon presenting a prescription;

(3) requesting the dispensing of a Schedule II controlled substance or a Schedule III controlled substance from a prescription issued by a prescriber with whom the pharmacist is unfamiliar, including a prescriber who is located outside Indiana or the prescriber is outside the usual pharmacy geographic prescriber care area; or

(4) presenting a prescription for a Schedule II controlled substance or a Schedule III controlled substance when the patient resides outside the usual pharmacy geographic patient population.

If an INSPECT program report is not immediately available, a pharmacist shall use the pharmacist's professional judgment in determining whether it is appropriate and in the patient's best interest to dispense a prescription before receiving and reviewing an INSPECT program report.

(b) The requirements under subsection (a) do not apply in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

SECTION 9. IC 25-27.5-2-7.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 7.5. "INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.**

SECTION 10. IC 25-27.5-5-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 4.5. (a) In addition to the rules adopted under IC 25-22.5-13-3, before initially prescribing a Schedule II controlled substance or a Schedule III controlled substance to a patient, a physician assistant shall:**

(1) check the INSPECT program for the available data on the patient for the twelve (12) month period immediately preceding the patient encounter; and

(2) appropriately use the INSPECT program data in the evaluation and treatment of a patient.

(b) If a patient's course of treatment with a Schedule II controlled substance or a Schedule III controlled substance prescribed by the physician assistant extends beyond three (3) months, a physician assistant shall:

(1) check the INSPECT program not less than every four (4) months for the available data on the patient for the preceding twelve (12) month period; and

(2) review the available INSPECT program data before issuing any new prescription or refills for the patient for a Schedule II controlled substance or a Schedule III controlled substance.

(c) If the INSPECT program data is not immediately available when the physician assistant is conducting a check under subsection (a) or (b), the physician assistant shall use the physician assistant's professional judgment in determining whether it is appropriate and in the patient's best interest to prescribe a Schedule II controlled substance or a Schedule III controlled substance before receiving and reviewing the INSPECT program data.

(d) The requirements under subsections (a) and (b) do not apply in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to

exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

SECTION 11. IC 25-29-1-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 10.5. "INSPECT program" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.**

SECTION 12. IC 25-29-1-17 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE MARCH 1, 2017]: **Sec. 17. (a) In addition to the rules adopted under IC 25-22.5-13-3, before initially prescribing a Schedule II controlled substance or a Schedule III controlled substance to a patient, a podiatrist shall:**

(1) check the INSPECT program for the available data on the patient for the twelve (12) month period immediately preceding the patient encounter; and

(2) appropriately use the INSPECT program data in the evaluation and treatment of a patient.

(b) If a patient's course of treatment with a Schedule II controlled substance or a Schedule III controlled substance prescribed by the podiatrist extends beyond three (3) months, a podiatrist shall:

(1) check the INSPECT program not less than every four (4) months for the available data on the patient for the preceding twelve (12) month period; and

(2) review the available INSPECT program data before issuing any new prescription or refills for the patient for a Schedule II controlled substance or a Schedule III controlled substance.

(c) If the INSPECT program data is not immediately available when the podiatrist is conducting a check under subsection (a) or (b), the podiatrist shall use the podiatrist's professional judgment in determining whether it is appropriate and in the patient's best interest to prescribe a Schedule II controlled substance or a Schedule III controlled substance before receiving and reviewing the INSPECT program data.

(d) The requirements under subsections (a) and (b) do not apply

in any of the following circumstances:

(1) The controlled substance is prescribed for a period not to exceed five (5) days.

(2) The controlled substance is prescribed for the treatment of cancer or another condition associated with cancer.

(3) The controlled substance is prescribed to a hospice program patient as defined by IC 16-25-1.1-5.

(4) The controlled substance is prescribed for administration in a nursing home or residential care facility.

SECTION 13. IC 35-48-7-11.1, AS AMENDED BY P.L.201-2015, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 11.1. (a) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(b) The board shall carry out a program to protect the confidentiality of the information described in subsection (a). The board may disclose the information to another person only under subsection (c), (d), or (g).

(c) The board may disclose confidential information described in subsection (a) to any person who is authorized to engage in receiving, processing, or storing the information.

(d) Except as provided in subsections (e) and (f), the board may release confidential information described in subsection (a) to the following persons:

(1) A member of the board or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive controlled substance prescription drug information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive

information from the INSPECT program.

(5) A controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(6) The state toxicologist.

(7) A certified representative of the Medicaid retrospective and prospective drug utilization review program.

(8) A substance abuse assistance program for a licensed health care provider who:

(A) has prescriptive authority under IC 25; and

(B) is participating in the assistance program.

(9) An individual who holds a valid temporary medical permit issued under IC 25-22.5-5-4 or **a temporary fellowship permit issued under** IC 25-22.5-5-4.6.

(10) Beginning March 1, 2017, a county coroner conducting a medical investigation of the cause of death.

(e) Information provided to an individual under:

(1) subsection (d)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (d)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(f) Before the board releases confidential information under subsection (d), the applicant must be approved by the INSPECT program in a manner prescribed by the board.

(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive controlled substance prescription drug information; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large

quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

(i) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (g) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(j) The board may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

(k) Except as provided in IC 25-22.5-13, this section may not be construed to require a practitioner to obtain information about a patient from the data base.

(l) A practitioner **who checks the INSPECT program for the available data on a patient** is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner:

(1) seeking ~~or not seeking~~ information from the INSPECT program; **and**

(2) in good faith using the information for the treatment of the patient.

The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(m) The board may review the records of the INSPECT program. If the board determines that a violation of the law may have occurred, the

board shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

(n) A practitioner who in good faith discloses information based on a report from the INSPECT program to a law enforcement agency is immune from criminal or civil liability. A practitioner that discloses information to a law enforcement agency under this subsection is presumed to have acted in good faith.

SECTION 14. IC 35-48-7-11.5, AS AMENDED BY P.L.109-2015, SECTION 55, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 11.5. (a) Each board described in IC 25-0.5-11-1 that regulates a health care provider that prescribes or dispenses prescription drugs shall do the following:

(1) Establish prescribing norms and dispensing guidelines that, if violated, justify the unsolicited dissemination of exception reports under section 11.1(d) of this chapter **not later than December 1, 2016.**

(2) Provide the information determined in subdivision (1) to the board.

(b) The exception reports that are disseminated based on the prescribing norms and dispensing guidelines established under subsection (a) must comply with the following requirements:

(1) A report of prescriptive activity of a practitioner to the practitioner's professional licensing board designee when the practitioner deviates from the dispensing guidelines or the prescribing norms for the prescribing of a controlled substance within a particular drug class.

(2) A reporting of recipient activity to the practitioners who prescribed or dispensed the controlled substance when the recipient deviates from the dispensing guidelines of a controlled substance within a particular drug class.

(c) The board designee may, at the designee's discretion, forward the exception report under subsection ~~(b)(2)~~ **(b)** to only the following for purposes of an investigation:

(1) A law enforcement agency.

(2) The attorney general.